

**REMARKS**

Claims 1-53 are pending. Claims 6-53 are withdrawn from consideration as drawn to nonelected inventions. Claims 3 and 5 are canceled herein. Claim 1 is amended herein. Support for these amendments can be found in the claims as filed, in paragraphs 82 and 89 of the specification, and elsewhere throughout the specification. Claim 54 is added herein. Support for new claim 54 can be found in the claims as filed, in paragraphs 49, 82 and 89 of the specification, and elsewhere throughout the specification. No new matter is believed to be added by these amendments. With the cancellation of claims 3 and 5, claims 1, 2, 4, 5 and 54 are under consideration.

**35 U.S.C. § 102(b)**

Claims 1, 2, 4 and 5 remain rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Thompson (U.S. Patent Number 7,029,859). Claim 5 is canceled herein, thus rendering this rejection moot as it pertains to claim 5. As amended herein, claim 1 relates to obtaining a breast tissue sample from the subject and assaying the level of androgen receptor in the breast tissue sample, wherein an increase in the level of androgen receptor as compared to the level of androgen receptor in normal breast tissue indicates an increased risk or presence of breast cancer. Nothing in U.S. Patent Number 7,029,859 discloses or suggests assaying the level of androgen receptor in a breast tissue sample. Accordingly, U.S. Patent Number 7,029,859 fails to disclose or suggest each and every element of the claim. Claim 1 is thus novel over U.S. Patent Number 7,029,859. Claims 2 and 4 depend directly on claim 1 and include all of the elements of claim 1. Thus, claims 2 and 4 are novel over U.S. Patent Number 7,029,859 for the same reason. Applicants request reconsideration and withdrawal of the novelty rejection of claims 1, 2 and 4 over U.S. Patent Number 7,029,859.

Claims 1, 2, 4 and 5 remain rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Fujimoto et al., *Laboratory Investigation* 80(9): 1465-1471 (2000) (“Fujimoto”). As set forth above, claim 5 is canceled herein, thus rendering this rejection moot as it pertains to

claim 5. As described above, claim 1 relates to obtaining a breast tissue sample and assaying the level of androgen receptor, wherein an increase in the level of androgen receptor as compared to the level of androgen receptor in normal breast tissue indicates an increased risk or presence of breast cancer. Fujimoto, however, fails to disclose or suggest assaying the level of androgen receptor in a breast tissue sample. Accordingly, Fujimoto fails to disclose or suggest each and every element of the claim. Claim 1 is thus novel over Fujimoto. Claims 2 and 4 depend directly on claim 1 and include all of the elements of claim 1. Thus, claims 2 and 4 novel over Fujimoto for the same reason. Applicants request reconsideration and withdrawal of the novelty rejection of claims 1, 2 and 4 over Fujimoto.

Claims 1, 2 and 4 remain rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Moinfar et al., *Cancer* 98(4): 703-711, (2003) (“Moinfar”). As described above, claim 1 relates to obtaining a breast tissue sample and assaying the level of androgen receptor in the breast tissue sample, wherein an increase in the level of androgen receptor as compared to the level of androgen receptor in normal breast tissue indicates an increased risk or presence of breast cancer. Moinfar only determines the presence of androgen receptor in breast cancer tissue samples and does not compare the level of androgen receptor in the breast tissue sample with a normal breast tissue sample. Accordingly, Moinfar fails to disclose or suggest each and every element of the claim. Claim 1 is thus novel over Moinfar. Claims 2 and 4 depend directly on claim 1 and include all of the elements of claim 1. Thus, claims 2 and 4 are novel over Moinfar for the same reason. Applicants request reconsideration and withdrawal of the novelty rejection of claims 1, 2 and 4 over Moinfar.

### **35 U.S.C. § 103(a)**

Claims 1-5 remain rejected under 35 U.S.C. § 103(a) as being obvious based on Fujimoto in view of U.S. Patent Number 7,029,859. Applicants respectfully traverse this rejection.

Claims 3 and 5 are canceled herein, thus rendering this rejection moot as it pertains to those claims. As stated above, both Fujimoto and U.S. Patent Number 7,029,859 fail to disclose or suggest obtaining a breast tissue sample and assaying the level of androgen receptor in the breast tissue sample, wherein an increase in the level of androgen receptor as compared to the level of androgen receptor in normal breast tissue indicates an increased risk or presence of

breast cancer. Therefore, the cited references, both alone or in combination, fail to disclose or suggest the claimed methods. The skill of those in the art fails to make up for this deficiency. Thus, claims 1, 2 and 4 are not obvious based on Fujimoto and U.S. Patent Number 7,029,859. Applicants respectfully request withdrawal of this rejection.

Claims 1-5 remain rejected under 35 U.S.C. § 103(a) as being obvious based on Moinfar in view of U.S. Patent Number 7,029,859. Applicants respectfully traverse this rejection. As set forth above, claims 3 and 5 are canceled herein, thus rendering this rejection moot as it pertains to those claims. As stated above, Moinfar only determines the presence of androgen receptor in breast cancer tissue samples. Moinfar does not teach that increased levels of androgen receptor in a breast tissue sample *as compared to normal breast tissue* is indicative of an increased risk or presence of breast cancer. Without comparing the level of androgen receptor in a breast tissue sample to the level of androgen receptor in normal breast cancer tissue, one of skill in the art could not determine if the level of androgen receptor in the breast tissue sample indicates the presence or risk of breast cancer. U.S. Patent Number 7,029,859 teaches androgen receptor as it relates to prostate cancer, not breast cancer. Therefore, the cited references, alone or in combination, fail to disclose or suggest the claimed methods. The skill of those in the art fails to make up for this deficiency. Thus, claims 1, 2 and 4 are not obvious over the Moinfar and U.S. Patent Number 7,029,859. Applicants respectfully request withdrawal of this rejection.

It is believed that all issues raised by the Examiner have been addressed. However, the absence of a reply to a specific rejection, issue, or comment does not signify agreement with or concession of that rejection, issue, or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

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The fee for the petition for extension of time is being paid concurrently herewith on the Electronic Filing System by way of Electronic Funds Transfer authorization. Please apply any other charges or credits to Deposit Account No. 50-5226.

Respectfully submitted,

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